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In re Application of	:
Lalanne et al	: Decision on Petition
Serial No. : 09/980,054	:
Filed : 15 February, 2002	:
Attorney Docket No. : 146.1374	:

This letter is in response to the Petition under 37 C.F.R. 1.144, filed on 14 June 2004.

BACKGROUND

This application is filed under 35 USC 371 of the National Stage filing of PCT/FR00/01567, which was filed on 08 June 2000.

A review of the file history shows that the Office made a lack of unity determination under 35 USC 121 and 372 dividing claims 1-18, 21, 24, 25, 27-29 into nineteen groups. In particular, the following lack of unity between groups V (nucleic acid) and group XI (polypeptide), and group XVIII (antibody) is at issue:

> Group V, original claims 1-10, 12-16, 27, 29 (in-part), drawn to a) polynucleotide encoding a polypeptide having at least 50 % identity with a sequence that is homologous to the polypeptide of SEQ ID NO: 12, and a complementary polynucleotide of polynucleotide of a).
>
> Group XI, original claims 11, 18, 27, 28 (in-part), drawn to a polypeptide having SEQ ID NO: 12, and analogs thereof.
>
> Group XVIII, original claims 24-25, 27 (in-part), drawn to antibody against polypeptide having SEQ ID NO: 12, or a fragment thereof.

Applicants elected group V, claims 1-10, 12-16, 27, 29 (in-part) with traverse in the response filed on 05 January 2004.

Examiner addressed applicants traversal regarding the restriction between groups V, XI and XVIII and rest of all the groups, and examined claims 1-10, 12-16, 27, 29 (in-part), drawn to

polynucleotide encoding a polypeptide having at least 50% identity with a sequence that is homologous to the polypeptide of SEQ ID NO: 12, and complements thereto. The examiner withdrew claims 11, 18, 21, 24-25, 28 as drawn to non-elected inventions. The lack of unity determination was made final in the office action mailed on 05 March 2004.

The petition to review the unity of invention requirement was filed on 14 June 2004, along with the amendments to the claims. The amendment cancels claims 1-18, 21, 24-25, 27-29 and adds new claims 30-46.

RELEVANT AUTHORITY

An international or a national stage application are considered to have unity of invention where there exists a "special technical feature" that defines a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. See PCT Rule 13.2; 37 CFR 1.475(a), (b)(1) and (2).

Unity of invention has to be considered in the first place only in relation to the independent claims in an international and not the dependent claims and
(i) If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims;
(ii) If however, an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on the claim need to be carefully considered. If there is no link remaining an objection of lack of unity a posteriori (that is, arising only after assessment of the prior art) may be raised. See ANNEX B: Unity of Invention Part 1 "Instructions Concerning Unity of Invention" MPEP AI-6 (Rev. 1. Feb. 2003).

DISCUSSION

The petition and application file history have been considered carefully.

The Petition present the following issues, each of which will be considered in turn:

(A) The examiner has set forth a restriction and not a lack of unity determination.
(B) The lack of unity determination differs from that in the international application.
(C) The inventions share a general inventive concept which meets the definition of Unity of invention under PCT Rule 13.2 and DNA, protein and antibody inventions should be examined together.
(D) The sequences should be examined together in view of MPEP 1850 and 803.04.

Concerning (A), Applicants are correct that the above-identified application is a national stage application submitted under 35 U.S.C. 371 to which "unity of invention", and not U.S. restriction practice is applicable. MPEP section 1893.03(d).

Applicants' concern that an "election/restriction" was set forth (see page 3, first full paragraph of petition) is unwarranted. The header "election/restriction" noted in the Office actions is

routinely used by the Office to designate either a restriction requirement under 35 USC 121 for US filed applications or to designate a lack of unity determination for national stage filings under 35 USC 371. Despite use of the term "restriction" in the Office actions, the examiner used the correct criteria for setting forth the lack of unity determination, i.e. 35 USC 121 and 372, PCT Rule 13.1, PCT Rule 13.2 and 37 CFR 1.499.

Concerning (B), the petition argues that the unity of invention in the US application should be identical to that in the PCT application. Unity of invention, like restriction practice under 35 USC 121 is discretionary. The examiner is not required to restrict. Conversely, the Office is not bound by any particular unity of invention determination set forth during PCT international national stage. Unity of invention is reviewed anew during PCT Chapter I, PCT Chapter II and during national stage. Unity may be lacking in the national stage filing even though all the claims were searched and examined together in the international application. For example, prior art found during national stage examination may be used to establish a new lack of unity determination among inventions which were searched and examined together in the PCT application.

Concerning (C), the lack of unity between the group V, nucleic acid encoding the peptide having amino acid sequence homologous to the amino acid sequence of SEQ ID NO: 12, group XI, the peptide having amino acid sequence homologous to the amino acid sequence of SEQ ID NO: 12 and group XVIII, antibody directed against a polypeptide having amino acid sequence homologous to the amino acid sequence of SEQ ID NO: 12 is at issue.

The newly added claims 30-46 correspond to the following groups:

> Group V, new claims 30-33, 36-44, drawn to nucleic acid sequence that encode protein of Candida species.
>
> Group XI, new claims 34-35, drawn to polypeptides.
>
> Group XVIII, new claims 45-46, drawn to antibodies.

Representative claims of group V:

Newly added claim 30: An isolated polynucleotide consisting of a polynucleotide sequence encoding SEQ ID NO: 12.
Newly added claim 36: An isolated polynucleotide consisting of a polynucleotide encoding a polypeptide according to claim 35.

Representative claims of group XI:

Newly added claim 34: An isolated polypeptide having an amino acid sequence SEQ ID NO: 12.
Newly added claim 35: An isolated polypeptide consisting of a polypeptide of Candida species having an amino acid sequence homologous with the amino acid sequences set forth in SEQ ID NO: 12, said homologue being essential for the viability of said Candida species.

Representative claims of group XVIII:

Newly added claim 45: An antibody directed against a polypeptide of claim 34.
Newly added claim 46: An antibody directed against a polypeptide of claim 35.

Further according to the PCT Rule 13.2, the special technical feature shall mean those technical features that define contribution which each of the claimed inventions, considered as whole makes over the prior art.

The technical feature of group V is polynucleotide.
The technical feature of group XI is polypeptide.
The technical feature of group XVIII is an antibody.

The polynucleotide is made of nucleic acids, and the polypeptide is made of amino acids. The polynucleotides of group V do not share a common structure or function or property with the polypeptide of group XI, or the antibody of group XVIII. The amino acid sequence of group XI peptides does not share a common structural feature with the amino acid sequence of group XVIII antibody sequences. It is noted that while the claims in groups V and XVIII refer back to the polypeptide of group XI, the claims in Groups V and XVIII do not require the polypeptides.

The petition argues that the antibodies of group XVIII share structural and functional features with the polypeptides of Group XI because the antibodies bind to the polypeptides. This is not convincing because the antibodies and the polypeptides lack corresponding structural and functional features. The antibodies contain constant and variable heavy and light chains, framework regions and complementarity determining regions that are absent from the polypeptide. The polypeptide functions as a translation elongation factor, a function the antibody clearly lacks. The antibody functions to bind antigen, a function the polypeptide lacks. For these reasons, the antibody and the polypeptide lack a same or corresponding technical feature. Thus, the polynucleotides of group V, the polypeptides of group XI, and the antibodies of group XVIII are not linked by the same or corresponding technical feature as defined by PCT Rule 13.2.

Moreover, PCT Rule 13.2 requires that any shared technical feature make a contribution over the prior art. It is noted that the technical feature of group XI is 'a polypeptide of Candida species having amino acid sequence homologous to the amino acid sequence of SEQ ID NO: 12, and the homologue is essential for the viability of Candida species.'

In the present instance none of the polynucleotides of group V, the polypeptides of group XI and the antibodies of group XVIII exhibit a corresponding special technical feature since Mendoza et al (Gene, vol. 229, 1999. pages 183-191) (cited by the examiner in the original lack of unity) teach translocation elongation factor 2 (CaEF2) encoded by an essential gene in Candida albicans. The reference teaches that the CaEF2 is essential for cell viability, and the gene product of CaEF2 is highly homologous to all eukaryotic eEF2 proteins. The reference protein encoded by CaEF2 would read on the polypeptide of original claim 11 and new claim 35 polypeptides.

The technical feature of group XI, 'the homologue of the peptide having amino acid sequence of SEQ ID NO: 12, and the homologue is essential for cell viability' is not considered as special technical feature in groups V and XVIIII, because Mendoza et al teach the Candida albicans protein which is essential for cell viability and reads on the instant claim 35 (group XI) polypeptide. The technical feature linking groups V, XI and XVIII does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art and hence the unity of invention is lacking.

Concerning (D), the petition argues that claims 44 and 45 directed to polypeptides, should be examined in a single group. See page 4, first paragraph of petition. In support of this position, the petition points to the following section of MPEP 1850,

> Further, claims directed to the selected sequences will be examined with claims drawn to any sequence combinations which have a common technical feature with the selected sequences. Nucleotide sequences encoding the same protein are considered to satisfy the unity of invention standard and will continue to be examined together.

This argument is not persuasive because (1) none of the claims recite a combination of nucleotide sequences (2) the nucleotide sequences which encode SEQ ID No 12 have not divided and (3) claim 44 recites a plasmid comprising nucleic acids and claim 45 recites an antibody which is not encoded by or binds to the nucleic acid, so it is not clear how the argument is commensurate in scope with the claims.

DECISION

Applicant's petition for reconsideration of Restriction requirement among groups V, XI, and XVIII under 37 CFR 1.144 is **DENIED** for the reasons set forth above.

Any request for consideration must be filed within two (2) months of the mailing date of this decision.

The application will be forwarded to the examiner for consideration of the response and amendment filed 9/104.

Should there be any questions regarding this decision, please contact Special Program Examiner Julie Burke, by mail addressed to Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at (571) 272-1600 or by Official Fax at 703-872-9306.

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